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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,968	07/28/2003	Michael Porat	03128CIP	4080
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EXAMINER BETTON, TIMOTHY E				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/627,968

Applicant(s)

PORAT, MICHAEL

Examiner

TIMOTHY E. BETTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8500)
Paper No(s)/Mail Date 3 sheets, 28 August 2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Individual Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's Remarks filed on 18 January 2008 has been acknowledged and duly made of record.

The essence of applicants' argument is drawn to the alleged unobviousness of the Cooper et al. and Chantler references. Applicants cite that the distinction in the inventive objective of instant claims is in the increased amount of a fungicide comprised in the sustained -delivery drug indicated as a cataractogenic.

In the instant Remarks, the applicant cites:

As the applicant has discovered, the problem with such compositions is that they destroy normal vaginal flora, resulting eventually in fungal infections, which increase the risk of contracting HIV and other diseases. In order to overcome this problem, applicant teaches adding to the composition "an effective amount of a fungicide to prevent the growth of fungi in the vagina which grow in the absence of natural bacterial flora destroyed by the antiseptic." Applicant believes that the amount of fungicide necessary to accomplish this result is higher than the amount necessary to prevent fungal growth in the composition itself. Thus, claims 9, 13 and 14 have been amended to require a minimum of 0.25% methyl paraben, as disclosed in the example at page 10, lines 20 et seq of the specification. The upper limit of claim 9, 1.0%, is found in the example at page 9, line 30 of the specification.

In response to the above disclosure, applicant's inventive objective is not clearly or adequately elucidated in the instant claims or specification. The distinction of the addition of an increased amount a fungicide, i.e., methyl paraben is not sufficiently described or explained to

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make it apparent to one of ordinary skill that the increased effective amount of methyl paraben has sufficiently eradicated or prevented fungal bacteria.

The examples and working models disclosed within the specification do not sufficiently point out comparative data or cumulative results clearly delineating the improved effect of additional methyl paraben on fungal growth in addition to preventing spoilage in storage.

The burden is on the applicant to prove that an effective amount of methyl paraben (of which the whole specification is absent) substantially eradicates the formation of particular fungal infections in the vaginal mucosa. The instant specification also seems to suggest that the increased concentration of a fungicide in a lubricant for sexual activity will remove every strain of a particular fungus common to the vaginal mucosa called *Candida albicans*. However, the skilled artisan is inclined to recognize that organisms develop resistance in addition to the necessity of proper and effective treatment. In other words, it has not been sufficiently disclosed in the specification that an effective amount has been identified or would be at all effective in view of the inventive objective and scope of the claimed invention.

In the examples of Cooper et al, the amount of methyl paraben used is 0.1% or 0.2%; see Example 2. This corresponds closely to the amount of methyl paraben used in known commercial compositions such as Predicat TM and K-Y® lubricants, both of which contain 0.1% by weight methyl paraben. The only function of methyl paraben in such compositions is to protect the compositions against fungal growth while in storage.

Again, the entire specification is silent upon any support and/or suggestion that an increased concentration of a fungicide will effectively prevent the occasion of herpes, syphilis, or HIV infection by keeping the growth of fungus in the vaginal mucosa at stasis.

Finally, one of skill would instantly recognize the reasonable expectation of optimization of characterization of components in such formulation through due experimentation. The amendment in the claims is not substantiated in any embodiment or explanation in the instant claims.

The skilled artisan may be inclined to recognize that the same amount of methyl paraben as indicated for preventing spoilage in storage may recognizably be an amount effective to cause stasis of fungal growth in the vaginal mucosa. The applicant may argue that prior art is absent of any indication drawn to controlling fungal growth in the vagina, however, as explained above the whole specification is silent as to how this increase in a fungicide actually achieves the scope of claimed invention.

In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. In *re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been required, In *re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, In *re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, In *re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367,

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370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974).

Thus, the claimed invention is made obvious based on statement immediately *supra*.

Applicant's Request to Withdraw Obviousness-Type Nonstatutory Double-Patenting

Page 4 of the Remarks filed 7 June 2007 discloses: Claims 1-12 and 14 have been rejected under the judicially created doctrine of obviousness-type double-patenting over claims 1 and 9 of US 6624198. Applicant recognizes the applicability of the double patenting rejection, and will file a terminal disclaimer to remove this rejection at such time as the disputed claims are found to be allowable.

However, there is no indication of a Terminal Disclaimer filed. Therefore, the Obviousness-Type Nonstatutory Double-Patenting rejection is maintained.

Obviousness-Type Nonstatutory Double-Patenting (Maintained)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or

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agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6624198 (Porat). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and Porat (USPN 6624198) claim a prophylactic lubricating/spermicidal composition for its use in sexual relations, including prevention of infection by HIV and other viruses.

The difference between the claimed invention of the instant application and the referenced patent 6624198 is that said patent discloses a practicing method with said composition, while the claimed invention of the instant application discloses said composition. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to select a species of the genus, observe similar properties and therapeutic effects and therefore use (as in a method for use).

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (USPN 4,242,359) and Chantler et al. (USPN 4,602,042).

Cooper et al teach a method for treating mammalian spermatozoa with amphipathic amines in order to induce loss of fertility and/or head-tail cleavage of the sperms under mild

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physiological conditions. In the presence of primary alkyl or cycloalkyl amines containing between 4 to 7 carbon atoms at concentrations of about 15 .lambda./ml, sperms are rapidly dissociated into heads and tails under physiological pH- and temperature-conditions. Further disclosed are topical contraceptive compositions containing amphipathic amines (abstract only).

Cooper et al. teach a cyclohexylamine containing composition. An aqueous solution of cyclohexylamine hydrochloride is incorporated into a hydroxyethylcellulose gel (commercial product K-Y Jelly) to form gel compositions containing 5-10% (w/w) of cyclohexylamine hydrochloride (column 7, lines 24-29).

Additionally, Cooper et al. teach the topical contraceptive composition may comprise supplementary topical antiseptic and germicidal agents, which are conventionally used in topical contraceptive compositions in addition to the amphipathic amine. Suitable supplementary contraceptive agents are, e.g., physiologically acceptable mono (alkylphenyl) ethers of polyethylene glycols wherein the alkyl group preferably contains between 1 and 10 carbon atoms and the polyethylene glycol preferably contains 2 to 12 ethyleneoxy units, such as **nonoxynol 9**, a p-nonylphenyl ether of a polyethylene glycol, mono (isooctylphenyl) ether of polyethylene glycol, mono (p-diisobutylphenyl) ether of polyethylene glycol and the like, or physiologically acceptable benzyldimethylalkylphenoxyethoxyethyl ammonium salts wherein the alkyl groups preferably contain 1 to 10 carbon atoms, or benzyldimethylalkyl ammonium salts wherein the alkyl groups preferably contain 8 to 18 carbon atoms, such as methylbenzethonium or benzethonium salts, e.g., chlorides, or benzalkonium chloride (column 8, lines 66-68 and column 9, lines 1-17).

Accordingly, Cooper et al. teach suitable jelly-formulations comprising gels containing a cellulose-derivative such as hydroxyethylcellulose, and optionally adjuvants such as thickening agents, e.g., soluble starch, and moistening agents, e.g., propylene glycol, into which an amount of between about 5 to about 10% by weight of an acid-addition salt of the amine is incorporated (column 9, lines 36-42). Thus, Cooper et al. teach HEC for use in the disclosed contraceptive jelly formulations.

Further, Cooper et al. teach a non-toxic topical contraceptive composition, which exhibit a high contraceptive activity without being irritating to the **vaginal mucosa** (column 1, lines 55-58).

Still further, Cooper et al. teach a topical contraceptive formulation according to the present invention, which are water soluble with specific pH ranges, [i.e.]; the active ingredients are incorporated into **water-soluble or water-dispersible** conventional pharmaceutical carriers. [...]. Other gel-forming and thickening agents are vegetable gums, which **are stable at pH values between 4 and 9**, preferably tragacanth or acacia, or physiologically acceptable synthetic thickening agents like polyvinyl **alcohols**, etc. (column 9, lines 18-35).

Cooper et al. cites percentages or mg/ 100 ml of contraceptive jellies in Example 2, where all the active ingredients according to instant claim 14 are in increased dose ranges, with the exception of methyl cellulose in comparison to HEC of instant invention. The methyl paraben component of instant invention is encompassed by the cited dosage ranges for methylparaben by Cooper et al.

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Cooper et al. teach 15 lambda of a composition as disclosed in one ml of the buffered mixture containing 10×10^7 spermatazoa, causes 93-99% of the spermatazoa to dissociate (column 6, lines 20-27).

Cooper et al. teach good results are normally attained via the composition in aqueous reaction media containing 1 and about 500 and 5 and about 500, respectively (column 6, lines 53-62).

Further, Cooper teach an amine concentration that prevents sperm motility at between 3-4% and 1-5%, respectively (column 7, lines 15-18).

Accordingly, Cooper et al. teach an amount of amphipathic amine at preferable concentrations as disclosed:

The topical contraceptive compositions contain a non-toxic amount of the above-described amphipathic amines per dosage unit which is effective to prevent the entry of any fertilizing sperms into the female cervix, but which is non-irritating to the vaginal mucosa. The concentration of the amphipathic amine within the contraceptive composition may vary considerably depending on which amine is used, as well as on the chemical and physical properties of the other ingredients of the composition. Usually, the amount of amphipathic amine is between about 0.1 and about 50%, preferably between about 0.5 and about 50%, especially between about 1 and about 25% in semi-solid compositions and between about 0.1 and about 15%, especially between about 0.2 and about 10% in solid compositions (column 8, lines 51-65).

Furthermore, Cooper et al teach additional adjuvants, which may be incorporated into these formulations, such as, **antiseptic agents** (column 9, line 61).

Chantler et al. teach contraceptive products specifically comprising chlorhexidine (column 2, line 45; column 4, lines 52 and 53).

Thus, it would have been *prima facie* obvious to the skilled artisan at the time of invention to at once recognize with a reasonable expectation of success, the combining of and/or the incorporating together of the teachings of Cooper et al. and Chantler et al. Cooper and Chantler et al. teach the central objective of instant claimed invention which are both drawn to contraceptive products.

Both said references are directed toward contraceptive products via disclosure and use of components such as a spermicide, an antiseptic, and a fungicide in specific percent (mg/100ml) dosage ranges. Chantler et al. relies on Cooper et al. for motivation to incorporate together based on the disclosure of antiseptic agents in Cooper et al. and embodiments of dosing concentration amounts and ranges. The Cooper et al. reference is replete with embodiments drawn to specific concentrations and dosage ranges which makes the claimed obvious of claimed invention. Additionally, Cooper et al. further provides motivation for Chantler et al via the specific disclosure of chlorhexidine in Chantler et al. Based upon the fact that Cooper et al. clearly teaches contraceptive jellies, and Chantler et al. teaches chlorhexidine as an effective contraceptive, one of ordinary skill in the art would be motivated to use the two together because they are both known for the same purpose.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617

TEB

